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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,950	03/20/2002	Frederic J de Sauvage	11669.0123USWO	4737
23552	7590	08/02/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			GAMETT, DANIEL C	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/088,950	<b>Applicant(s)</b> DE SAUVAGE ET AL.	
	<b>Examiner</b> Daniel C. Gamett, PhD	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06/07/2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17,20,23-25 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17,20,23-25 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The amendments of 06/07/2006 have been entered in full. Claims 15, 16, and 18 are cancelled. Claims 1-14, 19, 21-22, and 26-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 17, 20, 23-25, and 35 are under consideration.
2. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

### ***Rejections Maintained***

### ***Double Patenting***

4. The provisional obviousness-type double patenting rejection of Claims 17, 20, and 23-25 being unpatentable over claims 15-18, 20, and 23-25 of copending Application No. 10/663158, set forth in the office action of 12/07/2005, is maintained.

### ***Claim Rejections - 35 USC § 112***

5. Claims 17, 20, and 23-25 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is hereby extended to include

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new claim 35. Applicant's arguments filed 06/07/2006 have been fully considered but they are not persuasive. Applicants assert one skilled in the art is fully enabled to practice the claimed invention without undue experimentation based on evidence provided in the specification and known in the art. It has been noted, however, that at the time of filing, TCCR was a newly described receptor; its natural ligand was not known. While the prior art teaches that activation of TCCR should be generally useful to stimulate cell mediated immunity and lymphocyte proliferation, the prior art does not teach that a TCCR agonist (antibody or other) can be used to treat allergic diseases in which the specific effect of immune deviation is desired. The examples provided in the specification suggest that TCCR activity is needed for Th1 differentiation, and that the absence of TCCR activity is associated with the Th2 phenotype. Applicants argue persuasively that a post-filing reference, Lucas *et al.*, established that the TCCR ligand, IL-27, represents *an* important early trigger for Th1 differentiation *in vivo* (emphasis added). It remains clear, however, that IL-27 alone cannot induce Th1 differentiation. Therefore, even this post-filing reference does not diminish the unpredictability of the effects of a TCCR agonist antibody *in vivo*. Thus, Applicants' arguments do not alter the original finding that the instant specification as filed does not teach the skilled artisan how to treat Th2-mediated diseases such as asthma by administering antibodies. The added limitations of claim 35 do not overcome the lack of enablement of the method.

6. Further regarding enablement, Applicants cite MPEP 609.05(c) to the effect that refusal to consider the Huang *et al.* reference cited in the response filed 08/22/2005 was incorrect and constitutes a basis for according Applicant another full round of non-final prosecution on the

merits. The cited, and photocopied, section of the MPEP, however, clearly refers to *submitted* documents. In this case, no Huang *et al.* document can be found in the IFW and the Examiner has no evidence that this document was ever submitted.

***Claim Rejections - 35 USC § 102***

7. Claim 17 remains rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,792,850, issued August 11, 1998. Applicant's arguments filed 06/07/2006 have been fully considered but they are not persuasive. Applicants argue (p.12) that “the claimed method treats disorders involving antibody producing cells, involving cell mediated immunity”. From the context, it appears that Applicant intended “*not* involving cell mediated immunity” as indicated by the following: “The '850 patent fails to disclose expressly or inherently, methods of treating such diseases by administering an agonist of TCCR. Indeed, the '850 patent expressly discloses the opposite, i.e., that agonists can be used to stimulate cell mediated immunity and lymphocyte proliferation (col. 15, lines 3-15)”. First, the amended claim 17 is not limited to treating disorders involving antibody producing cells, as it is drawn to a method of treating “an infectious disease”. Infectious diseases are combated by both cell-mediated and antibody mediated responses. Treatment of infections is taught in the '851 patent further in the same sentence quoted by Applicant. Therefore, as previously noted, the '851 patent anticipates the instant claims by teaching administration of the same agonist antibodies to the same patient population, at least with regard to treatment of an infectious

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disease. This fact distinguishes the instant case from *In re* Marshall, cited by Applicant (p.

11) with regard to inherency.

### *Conclusion*

8. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG

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31 July 2006

  
**DAVID S. ROMEO**  
**PRIMARY EXAMINER**